179

(4)

No. 10-762

Supreme Court, U.S.
FILED
JAN 7 - 2011
OFFICE OF THE CLERK

In The
Supreme Court of the United States

LOUISIANA WHOLESALE DRUG CO., INC., CVS PHARMACY, INC., RITE AID CORPORATION, ARTHUR'S DRUG STORE, INC.,

Petitioners,

v.

BAYER AG, BAYER CORP., formerly doing business as Miles Inc., HOECHST MARION ROUSSEL, INC., THE RUGBY GROUP, INC., WATSON PHARMACEUTICALS, INC., BARR LABORATORIES, INC.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit

BRIEF OF *AMICUS CURIAE* THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PETITIONERS

PAUL E. SLATER
SPERLING & SLATER, P.C.
55 West Monroe Street, Suite 3200
Chicago, IL 60603
(312) 641-3200
pes@sperling-law.com
Counsel for Amicus Curiae American Antitrust Institute

COCKLE LAW BRIEF PRINTING CO (800) 225-6964
OR CALL COLLECT (402) 342-2831

TABLE OF CONTENTS

	Page
INTEREST OF *AMICUS CURIAE*	1
BACKGROUND	2
STATEMENT OF THE CASE	7
SUMMARY OF ARGUMENT	12
REASONS FOR GRANTING THE PETITION	14
I. The Court Should Grant Review Because the Decision Below Was Wrongly Decided and Directly Conflicts with the Decisions of This Court	14
II. The Court Should Grant Review in Order to Resolve the Split Among the Circuits	19
CONCLUSION	21

TABLE OF AUTHORITIES

Page

CASES

Andrx Pharmaceutical Inc. v. Biovail Corp. Intl., 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002) 5, 13, 20

Arkansas Carpenters Health and Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010) .....*passim*

In re Berwyn E. Etter, 756 F.2d 852 (Fed. Cir. 1985) 17

Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found., 402 U.S. 313 (1971) 17

In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004) 10, 13, 19

In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009) .....*passim*

Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litigation), 466 F.3d 187 (2d Cir. 2005) .....*passim*

Microlux Biosystems, Inc. v. Biowhittaker, Inc., 172 F.Supp.2d 680 (D. Md. 2000) 16

Palmer v. BRG of Georgia, Inc., 498 U.S. 46 (1990) 15, 16

Schering-Plough Corp. v. Federal Trade Commission, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) 6, 13, 20

Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1983) 17

TABLE OF AUTHORITIES – Continued

Page

In re Terazosin Hydrochloride Antitrust Litigation, 352 F.Supp.2d 1279 (S.D. Fl. 2005) 11, 20

U.S. v. Glaxo Group, Ltd., 410 U.S. 52 (1973) 17

U.S. v. Microsoft Corp., 253 F.3d 34 (D.C. Cir. 2001) 4, 16

U.S. v. Singer Mfg. Co., 374 U.S. 174 (1963) 15

U.S. v. Topco Assoc., 405 U.S. 596 (1972) 15, 16

Valley Drug Co. v. Geneva Pharms., Inc., 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 934 (2004) 6

STATUTES

15 U.S.C. §1 13

21 U.S.C. §355 ..... 2, 3, 17

35 U.S.C. §271 3

35 U.S.C. §282 5

OTHER AUTHORITIES

Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) 4

XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b (2d ed. 2005) 4

In re Schering-Plough Corp., FTC Docket No. 9297, 2003 WL 22989651 (2003) 5, 10, 18

INTEREST OF *AMICUS CURIAE*[1]

The American Antitrust Institute ("AAI") is an independent non-profit education, research, and advocacy organization. Its mission is to advance the role of competition in the economy, protect consumers, and sustain the vitality of the antitrust laws. The Advisory Board of AAI, which serves in a consultative capacity,[2] consists of prominent antitrust lawyers, law professors, economists, and business experts. *See* http://www.antitrustinstitute.org.

AAI's Board of Directors has authorized the filing of this brief because it believes that the Second Circuit's economic and legal reasoning is flawed and seriously threatens competition. If left standing, the opinion will undermine the careful statutory scheme that seeks to prevent weak or narrow patents from blocking the market entry of generic drugs and reducing competition. The stakes for consumers are high. The opinion of the Second Circuit Court of Appeals will encourage and allow brand name pharmaceutical

---

[1] All parties were advised of the AAI's intention to file an *amicus* brief more than ten days prior to its due date. The written consents of all parties to the filing of this brief have been lodged with the Clerk. No counsel for a party has authored this brief in whole or in part, and no person or entity other than AAI or its counsel has made a monetary contribution to the preparation or submission of this brief.

[2] The AAI is managed by its Board of Directors. The individual views of members of the Advisory Board may differ from the positions taken by AAI.

manufacturers to pay generic competitors to keep their cheaper generic drugs off the market.

BACKGROUND

Competition from generic drug manufacturers is one of the few constraints on the rising cost of brand-name drugs. Generic drugs typically sell for a fraction of the price of their branded counterparts. That price differential allows generic entrants to quickly capture a majority of the unit sales from the higher priced branded drugs, thereby saving consumers billions of dollars on blockbuster drugs such as Ciprofloxacin ("Cipro").

In order to encourage market entry by generic drugs and the attendant price competition, Congress promulgated the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act"). The Hatch-Waxman Act encourages generic firms to challenge the validity of pharmaceutical patents by allowing them to statutorily infringe the patent without subjecting themselves to infringement damages. Specifically, when a generic firm applies to the FDA for the right to sell a generic drug, it can certify, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), either that the pertinent brand patent is invalid or that the generic version of that drug does not infringe the patent. This so-called "Paragraph IV Certification" by a generic firm is made an act of infringement by the Hatch-Waxman Act and gives the patentee

an immediate cause of action against the potential market entrant. 35 U.S.C. §271(e)(1)-(2). Because the generic firm has neither made nor sold the generic product, its act of infringement causes no damage to the patentee. As stated in the opinion below, "the Hatch-Waxman Act . . . allow[s] generic manufacturers to challenge the validity of the patent without incurring . . . the risks of damages from infringement." *Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, 604 F.3d 98, 101 (2d Cir. 2010).

The Hatch-Waxman Act further encourages generic firms to challenge pharmaceutical patents by giving the first generic firm to make a Paragraph IV Certification a 180-day period of exclusivity. 21 U.S.C. §355(j)(5)(B)(iv). During this period of exclusivity, the generic firm will be the only low-priced alternative to the patented drug and it may be able to obtain a foothold on generic sales that will last beyond the 180-day period. The 180-day period of exclusivity begins to run when the generic firm begins marketing its version of the drug or when a final judicial order issues determining that the patent is either invalid or not infringed, whichever occurs first. *Id.*

This congressional scheme, when not circumvented by the type of conduct at issue in this case, has succeeded in encouraging generic firms to challenge and set aside through litigation weak pharmaceutical patents. According to the Federal Trade Commission ("FTC"), when generic firms have been sued for infringement after making a Paragraph IV Certification, they have prevailed at the patent trial

in 73% of the tried cases. Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

In order to avoid such judicial scrutiny of their patents many pharmaceutical patentees have entered into "reverse" or "exclusion" payment settlement agreements. Under these agreements, the generic firm typically (1) drops its challenge to the validity of the patent or its denial of the patentee's claim of infringement, and (2) agrees to respect the patent and not attempt to enter the market until it is about to expire. In return, the patentee pays the generic challenger tens of millions or hundreds of millions of dollars. These payments are made by the patentee to the generic firm even though the generic firm has not alleged that the patentee owes it any money. Such reverse payments are fairly characterized as the purchase by the patentee of the generic firm's agreement to cease its efforts to enter the market and compete against the patented drug.

It is unlawful under the Sherman Act to pay an actual or potential competitor to stay out of the market. This rule applies regardless of the degree of certainty that the potential competitor, absent the payment, would, in fact, be able to successfully enter the market. *See, e.g.,* XII Herbert Hovenkamp, ANTITRUST LAW: AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION ¶ 2030b at 213 (2d ed. 2005); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*). The Court of Appeals for the

Sixth Circuit therefore held in *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 914 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004), that a reverse exclusion payment agreement between a generic manufacturer and a patentee is "a plain vanilla horizontal agreement to restrain trade" which is unlawful *per se*. Despite the rebuttable presumption of patent validity under 35 U.S.C. §282, the Sixth Circuit held that some patents are "'paper tiger[s]' incapable of deterring a generic producer from entering the market. . . ." 332 F.3d at 915. The Court further noted that if the patentee "had . . . been confident of the independent durability of its patent and the validity of its infringement claim, it would not have paid $89 million to effect what the patent and infringement suit had already accomplished." *Id.* The D.C. Circuit, considering the same agreement that was at issue in *Cardizem*, likewise held that it was anticompetitive. *Andrx Pharm., Inc. v. Biovail Corp. Intl.*, 256 F.3d 799, 813 (D.C. Cir. 2001) (stating that a reverse exclusion payment was "presumably in return for something that Andrx would not otherwise do, that is, delay marketing of its generic").

The FTC has similarly held that if the patent alone was sufficient to deter market entry then a reverse payment to a generic firm would not be necessary. As a result, the FTC held that reverse payment agreements should be deemed presumptively anticompetitive and unlawful. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651

(Dec. 8, 2003). That decision, however, was vacated by the Court of Appeals for the Eleventh Circuit. *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006). The Court relied heavily on the opposite presumption – *i.e.*, that the patent should be presumed valid. *Id.* at 1066. Indeed, the Court went so far as to presume that the accused product infringed the patent in question. *Id.* ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they prove . . . that their products . . . did not infringe Schering's patent"). *See also Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003), *cert. denied*, 543 U.S. 934 (2004).

The opinion below goes a step beyond the Eleventh Circuit analysis. The Second Circuit holds that exclusion payments are *per se lawful* unless the plaintiff proves that the patent was procured by fraud or that the infringement action is brought in such bad faith as to constitute a sham. 604 F.3d at 106. Under this approach, mere invalidity or non-infringement of the patent is insufficient to allow the reverse payment agreement to be challenged under the antitrust laws. Unless accompanied by egregious conduct such as fraud or bad faith, the Second Circuit places reverse payment agreements beyond the reach of the Sherman Act, as a matter of law.

As explained below, the AAI believes it is time for this Court to resolve the question of what standard should be used to determine whether a reverse

exclusion payment agreement is beyond the reach of the antitrust laws.

STATEMENT OF THE CASE

In the case below, Bayer owned the patent to ciprofloxacin hydrochloride ("Cipro"), one of the most prescribed antibiotics in the world. The generic manufacturer, Barr, was a potential entrant into the Cipro market. In 1991, twelve years before the Cipro patent was to expire, Barr filed a Paragraph IV Certification indicating that it would enter the Cipro market with a generic version of that drug. 604 F.3d 98, 100-01. In response, Bayer sued Barr for infringement. *Id.* at 101-02.

Two weeks before the patent trial was to commence, Bayer and Barr agreed to a reverse payment settlement. *Id.* at 102. Bayer, which faced no claim for money damages, agreed to pay Barr, the accused infringer, $398 million. In return, Barr agreed not to enter the Cipro market until only six months remained on the patent and stipulated that the patent was valid. *Id.*; Pet. App. at 42(a).

Direct purchasers of Cipro filed an antitrust suit alleging that the reverse payment agreement was a horizontal combination between competitors that allocated the Cipro market to Bayer. *Id.* at 102-03. The antitrust trial court granted summary judgment for the defendants. It held that whether the reverse payment agreement had adversely affected

competition for ciprofloxacin was not "the crux of the matter." *Id.* Rather the *only* pertinent question was whether the adverse effects on competition stemming from the reverse payment agreement were within the scope of the Cipro patent. *Id.* The trial court reasoned that any other "approach would undermine the presumption of validity of patents in all cases." *Id.*

The Second Circuit affirmed. It did so reluctantly, noting that after the trial court entered judgment for the defendants in *Cipro*, a panel of the Second Circuit had decided *Joblove v. Barr Labs., Inc. (In re Tamoxifen)*, 466 F.3d 187 (2d Cir. 2005), and "held that reverse payment settlements of patent lawsuits do not violate antitrust laws." Pet. App. 10a. The Second Circuit stated that "[b]ecause *Tamoxifen* is dispositive of plaintiffs' claims, we AFFIRM." *Id.* But, the Second Circuit also stated "because of the 'exceptional importance' of the antitrust implications of reverse exclusionary payment settlements of patent infringement suits, we invite plaintiffs-appellants to petition for rehearing in banc" so that the *Tamoxifen* holding could be reconsidered. Pet. App. 10a.

In *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2005) ("*Tamoxifen*"), a pharmaceutical patentee agreed to pay a generic manufacturer $21 million and the generic manufacturer agreed not to challenge the validity of the *Tamoxifen* patent or enter the market with a generic version of the patented drug until the patent expired. This reverse payment settlement agreement was entered

into after the patent was held invalid at trial, but before the appeal. *Id.* at 193-94.

Direct purchasers of the patented drug subsequently sued the patentee and the generic manufacturer alleging that the reverse payment agreement violated the Sherman Act. The trial court granted the defendant's motion to dismiss. The Second Circuit affirmed, holding that the antitrust plaintiffs had failed, as a matter of law, to state a claim. Specifically, this Court stated:

> So long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is *presumably entitled*: a lawful monopoly over the manufacture and distribution of the patented product.

and

> Unless and until the patent is shown to have been procured by a fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law as long as competition is restrained only within the scope of the patent.

Id. at 208-09, 213 (emphasis added).

In so holding, the *Tamoxifen* Court acknowledged that the reverse payment agreement would allow the patentee to continue earning monopoly profits, which it could then share with the retreating generic entrant,

and further acknowledged that as a result of the reverse payment agreement consumer prices would likely be higher than if market entry had occurred. *Id.* at 208-09. Nonetheless, the Second Circuit held that reverse payment agreements were necessarily beyond the reach of the antitrust laws because the patentee was "presumably entitled" to its "monopoly over the manufacture and distribution of the patented product." *Id.* at 213. In effect the Court presumed that the patent was valid and infringed and that the patentee's monopoly was, therefore, lawful.

In following *Tamoxifen*, the *Cipro* Court was not unaware that the *Tamoxifen* decision was controversial and contrary to the views of the FTC, United States Department of Justice and other Circuits. 604 F.3d at 104-05.[3] The Second Circuit acknowledged that the FTC "has long insisted that reverse exclusionary payment settlements violate antitrust law"; that the United States believes reverse payment patent settlements should be deemed presumptively illegal; and that "many academic commentators share [that] view." 604 F.3d at 104-05. The Second Circuit further acknowledged that in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003),

---

[3] United States: *See* Brief *Amicus Curiae* of the United States in Support of Rehearing in Banc, submitted to the Second Circuit Court of Appeals in the case below, at 9-10, 28-29; *also* 604 F.3d at 109. FTC: *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (FTC 2003), *rev'd.*, 402 F.3d 1056 (11th Cir. 2005).

the Sixth Circuit held reverse exclusionary payment agreements "to be *per se* illegal." 604 F.3d at 105. *See also In re Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279 (S.D. Fl. 2005) (holding reverse exclusionary payment agreements *per se* unlawful).

Nonetheless, the *Cipro* Court adhered to the *Tamoxifen* holding that "the plaintiffs had no antitrust claim because a patent holder is entitled to protect its 'lawful monopoly over the manufacture and distribution of the patented product.'" 604 F.3d at 105-06. The *Cipro* Court then explicitly adopted the *Tamoxifen* test that unless the patent was procured by fraud or the claim of infringement was an objectively baseless sham, an injury to competition could not be found. 604 F.3d at 106. The *Cipro* Court concluded that it was bound by precedent to follow *Tamoxifen*, which had "rejected antitrust challenges to reverse payments as a matter of law." *Id.*

The Petitioners herein accepted the Second Circuit's invitation to file for rehearing in banc. Their petition was denied. Pet. App. 2a. Circuit Judge Rosemary S. Pooler dissented. Judge Pooler noted that reverse payment settlement agreements had become increasingly common and that the *Tamoxifen* decision "has played a significant role in encouraging this unfortunate practice." Pet. App. 3a-4a. Judge Pooler further noted that the FTC had found that, subsequent to *Tamoxifen*, 53 reverse payment pharmaceutical patent settlements had been executed and that those settlements cost consumers approximately $3.5 billion

per year. Pet. App. 4a-5a. Judge Pooler agreed with the position of the United States that the *Tamoxifen* rule was "incorrect" (Pet. App. 7a) and stated that reverse payment settlement agreements "serve no obvious redeeming social purpose." Pet. App. 5a. Dissenting from the denial of rehearing in banc, Judge Pooler stated "[i]t will now be up to the Supreme Court or Congress to resolve the conflict among the Courts of Appeals." Pet. App. 8a.

SUMMARY OF ARGUMENT

The decision below should be reviewed by this Court for two reasons. First, the rule announced in *Tamoxifen* and followed in *Cipro* is incorrect and seriously compromises the public interest in having competition drive pharmaceutical prices lower. The holding below is incorrect because the Second Circuit wrongly presumes that the Cipro patent is valid and infringed unless the patentee is guilty of fraud or bad faith. In so doing, the Second Circuit presumes its conclusion in all but those cases where the patentee is guilty of intentional misconduct. In actuality, the presumption of patent validity is merely a procedural rule that assigns burdens of proof. It is not a presumption of substantive validity and it is not irrebuttable except in cases of bad faith or fraud. Furthermore, the law has never recognized a presumption of infringement. By presuming that the patent is valid and infringed, the Second Circuit circumvents the controlling decisions of this Court.

Those decisions hold that a horizontal agreement between a market participant and a potential entrant, that eliminates the possibility of entry, unlawfully restrains competition. This Court has also held that a patent settlement agreement that incorporates anticompetitive terms is violative of the Sherman Act. The need to apply these holdings to the facts of the *Cipro* litigation should not have been obviated by unsupported presumptions.

Second, the decision below sharply conflicts with the decision of the Sixth Circuit in *In re Cardizem Antitrust Litigation*, 332 F.3d 896, 907 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharm., Inc. v. Kroger Co.*, 543 U.S. 939 (2004). In that case, the Court held that reverse payment patent settlements are *per se* violations of §1 of the Sherman Act (15 U.S.C. §1). This also appears to be the rule in D.C. Circuit. *Andrx Pharmaceutical Inc. v. Biovail Corp. Intl.*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002).

The Eleventh Circuit has rejected the *per se* approach but also disagrees with the *Cipro/Tamoxifen* line of decisions. It holds that reverse payment agreements are unlawful if the generic firm proves that the patent is either invalid or not infringed. *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006).

The United States and the FTC take still another course. They both assert that reverse payment patent settlements are presumptively unlawful

These various rules and approaches have led to inconsistent application of the law and uncertainty with regard to a matter of significant public concern. The AAI respectfully submits that this Court should review the decision below so that the correct rule will be uniformly applied to reverse payment patent settlements.

REASONS FOR GRANTING THE PETITION

I. The Court Should Grant Review Because the Decision Below Was Wrongly Decided and Directly Conflicts with the Decisions of This Court

AAI respectfully submits that the case below and its foundation, *Tamoxifen*, were wrongly decided. Both decisions are based on two interrelated and incorrect propositions. First, both cases confuse the right of a patentee to exclude others from making the patented device with a supposed right to pay potential competitors not to test the validity of a patent which may or may not be valid or infringed. Second, both decisions misapprehend the legal presumption of patent validity. That presumption is a procedural tool that merely determines who has the burden of proof when a patent is challenged. It is not a substantive rule of patent validity and is not irrebuttable in the absence of fraud or bad faith – as *Tamoxifen* clearly holds.

This Court has held that the antitrust laws protect both actual and potential competition. Thus,

the Sherman Act prohibits not only agreements that restrain competition, but also those that restrain market entry. *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990) (agreement between competitor and potential entrant that the potential entrant would not attempt to enter the competitor's market held to unlawfully restrain competition); *U.S. v. Topco Assoc.*, 405 U.S. 596 (1972) (agreement between competitors not to attempt to enter each other's market held unlawful). Furthermore, the fact that otherwise anti-competitive terms are embodied in a patent settlement agreement provides no defense. If the terms of a patent settlement agreement unreasonably restrains competition, they violate the Sherman Act. *U.S. v. Singer Mfg. Co.*, 374 U.S. 174 (1963) (patent settlement agreement excluding foreign competitors from the U.S. market held *per se* unlawful).

When a market is dominated by a competitor with a blocking patent, a potential market entrant must successfully defeat the patentee's contention that the patent is valid and that the competitor's device infringes it in order to successfully enter the market. The necessity of accomplishing this task is analytically no different than the need for a new entrant to build a plant or procure access to scarce materials. In either event, the new entrant must invest time, effort and capital in the pursuit of a goal that it might or might not successfully achieve. No one would suggest, however, that an agreement to pay a potential market entrant millions of dollars not to build a plant or attempt to enter the market would be lawful. To the contrary, this Court has repeatedly

held that an agreement precluding a potential competitor from entering the market is "unlawful on its face." *Palmer*, 498 U.S. at 50; *Topco*, 405 U.S. at 608 (agreement precluding potential competitors from entering a co-competitor's market held *per se* unlawful).[4] As stated by the United States in its *amicus* brief to the Second Circuit in support of rehearing in banc in the case below, the Sherman Act does not permit patent holders "to contract their way out of the statutorily imposed risk that the patent litigation could lead to invalidation of the patent while claiming antitrust immunity for that private contract." 604 F.3d at 108-09. The United States further argued that *Tamoxifen* "inappropriately" allows patentees to do just that while offering "no protection to the public interest in eliminating undeserved patents." *Id.*

Tamoxifen's holding that reverse payment agreements do not injure competition because the patentee is "presumably entitled" to its patent monopoly (466 F.3d 208-09, 213) is also incorrect. The patent law

---

[4] *See also* XII Herbert Hovenkamp, ANTITRUST LAW, ¶ 2030(b) at 213 (2d ed. 2005) ("the law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition"); *Microsoft*, 253 F.3d at 78-79 (rejecting the contention that no injury to competition could be shown unless the new entrant, in fact, would have successfully developed its new product); *Microlux Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F.Supp.2d 680, 685-86 (D. Md. 2000) (agreement preventing plaintiff from obtaining needed materials held to be "obvious[ly]" anticompetitive even though the plaintiff would have needed to overcome numerous obstacles to successfully enter the market).

provides no such iron-clad presumption in favor of validity. Indeed, Congress specifically provided for judicial review of patent validity and the presumption of validity is only "a procedural device, not substantive law." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983). It merely assigns burdens to patent litigants and does not "acquire an independent evidentiary role in any [other] proceeding." *In re Berwyn E. Etter*, 756 F.2d 852, 856 (Fed. Cir. 1985). Indeed, far from presuming substantive validity, the Hatch-Waxman Act and the opinions of this Court explicitly encourage generic manufacturers to challenge patents and protect the public interest by testing them in Court. *See* 21 U.S.C. §355(j)(5)(B)(iv) and (vii)(IV); *Blonder-Tongue Labs, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971) (patent law "encourage[s] authoritative testing of patent validity"); *U.S. v. Glaxo Group, Ltd.*, 410 U.S. 52, 58 (1973) ("it is . . . important to the public that competition should not be repressed by worthless patents").

AAI does not here address the question of what substantive rule should be employed to determine whether a reverse payment agreement unreasonably injures competition. AAI submits that the question should be addressed on the merits by this Court. For current purposes, AAI submits only that the holding in *Tamoxifen*, adopted and followed in the decision below, is plainly incorrect and raises questions of exceptional importance to the public and to the proper enforcement of the antitrust laws in a patent setting.

If a pharmaceutical patent is valid and infringed, then the patentee has the right under the patent statutes to exclude the generic drug from the market without unlawfully restraining competition. The question, however, which is raised by *Cipro* and *Tamoxifen*, is whether a patentee can pay a potential generic entrant not to test the validity of the patent or whether the patent is infringed by the generic version of the drug without running afoul of the antitrust laws. Clearly, if the patent is either invalid or not infringed, then the reverse payment agreement acts as a restraint on potential horizontal competition that the patent statutes do not permit. The question, of course, is what analytical rule structure will be used to determine whether competition was unreasonably restrained when it is the infringement suit itself that has been settled. In its *amicus* brief to the Second Circuit, the United States proposed that a rule of reason be employed and that "reverse payments substantially in excess of anticipated litigation costs" should be deemed "presumptively unlawful" unless the defendant can provide "a reasonable explanation of the payment." U.S. *Amicus* Brief, 9-10, 28-29; 604 F.3d at 109. The FTC has similarly taken the position that reverse payment settlement agreements should be deemed presumptively unlawful. *In re Schering-Plough Corp.*, FTC Docket No. 9297, 2003 WL 22989651 (2003), *rev'd*, 402 F.3d 1056 (11th Cir. 2005). Other approaches are possible. AAI respectfully submits, however, that the *Cipro/Tamoxifen* approach, which allows the antitrust laws to function only where the patentee is guilty of fraud or has acted in

bad faith, gives far too much latitude to the patentee and the generic entrant to pursue their own financial gain and far too little protection to the public's interest in competitive markets.

II. The Court Should Grant Review in Order to Resolve the Split Among the Circuits

It is undisputed that the circuits are split on whether reverse payment agreements "fall within the scope of the patent holder's property right or whether such settlements are properly characterized as illegal market sharing agreements." 604 F.3d at 104-05. Indeed, the Court below acknowledged that the "[a]uthorities are divided on this question." *Id.* at 105.

In the Second Circuit the *Tamoxifen/Cipro* rule prevails and reverse payment agreements are presumed, as a matter of law, not to violate the Sherman Act unless the patentee is guilty of fraud or bad faith. The questions of whether the patent is merely weak, invalid or not infringed are irrelevant to the analysis. The Federal Circuit agrees with the Second Circuit's formulation. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).

The Sixth Circuit has taken the diametrically opposed position. In *In re Cardizem CD Antitrust Litigation*, the Court characterized the reverse payment settlement of $89.83 million as a payment by the patentee to the generic firm to keep "its generic product off the market" (332 F.3d at 907) and stated:

> There is simply no escaping the conclusion that the Agreement . . . was, at its core, a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade.

332 F.3d at 908. This also appears to be the approach taken by the D.C. Circuit. *Andrx Pharm., Inc. v. Biovail Corp. Intl.*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002). *See also In re Terazosin Hydrochloride Antitrust Litigation*, 352 F.Supp.2d 1279 (S.D. Fl. 2005) (reverse payment settlement agreement held *per se* unlawful).

The Eleventh Circuit has charted a third course. In *Schering-Plough Corp. v. Federal Trade Commission*, 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006), it explicitly rejected the use of the *per se* rule or the rule of reason. 402 F.3d at 1064, 1065 ("neither the rule of reason nor the *per se* analysis is appropriate"). Rather than analyzing the competitive effect of the agreement, *Schering* requires a determination of whether the patent is in fact valid and infringed and places the burden of proof on the antitrust plaintiff. Thus, *Schering* holds that market exclusion, even if it injures competition, does not go beyond what is permitted by the patent "unless and until" the patent is proved invalid or not infringed. 402 F.3d at 1066-67. This, of course, requires the relitigation of the patent issues in the antitrust case, but at least it does not simply presume validity and infringement as does the *Cipro/Tamoxifen* approach.

AAI respectfully submits that the divergence among the Circuits is dramatic and troublesome. The importance of generic entry into pharmaceutical markets and the cost to consumers if cases are wrongly decided strongly supports granting the Petition. There should be one national approach for how reverse payment pharmaceutical settlement agreements are treated; and that approach should be consistent with the intent of the Hatch-Waxman Act, the Sherman Act, and the patent statutes, all of which encourage or permit challenges to patents that may be invalid or not infringed.

CONCLUSION

For the reasons stated above, the American Antitrust Institute respectfully submits that the Court should grant the petition for certiorari.

Dated: January 6, 2011

Respectfully submitted,

PAUL E. SLATER
SPERLING & SLATER, P.C.
55 West Monroe Street
Suite 3200
Chicago, IL 60603
(312) 641-3200
pes@sperling-law.com
Counsel for Amicus Curiae
American Antitrust Institute